



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/612,661	03/08/96	CHRISTENSEN	ISIS-2169

HM31/0420
JOHN W CALDWELL
WOODCOCK WASHBURN KURTZ MACKIEWICZ
AND NORRIS
ONE LIBERTY PLACE - 46TH FLOOR
PHILADELPHIA PA 19103

EXAMINER
MARSCHER, A

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/20/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/612,661

Applicant(s)

Christensen et al.

Examiner

Marschel, Ardin

Group Art Unit

1634



☒ Responsive to communication(s) filed on 12/8/97 and 2/9/98

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 and 11-21 is/are pending in the application.

~~Of the above, claim(s) 9 and 10 have been canceled.~~

~~CLAIMS 9 AND 10 HAVE BEEN CANCELED.~~

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 and 11-21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1634.

The amendments, filed 12/8/97 and 2/9/98, has been approved for entry and has been entered. The following office action contains newly applied rejections and/or objections. Because of these newly applied rejections and/or objections, the finality of the office action, mailed 8/5/97, is hereby withdrawn.

Applicants' arguments, filed 2/9/98, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because the specification on pages 19 and 21, lines 24 and 14, respectively, contains a sequence without a SEQ ID NO. Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action.

Claims 1-8 are rejected under 35 U.S.C. 112, first

paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Reconsideration of the instant disclosure as filed has failed to reveal written basis, as filed, for the limitations amended into claim 1 given as either vinyl polymerization-type linkages, phosphodiester analog linkages, or combinations thereof. These limitations were suggested by the examiner in a previous action as enabled in the prior art. The suggestion of these limitations is regreted by the examiner in that "written" basis for them is not present in the instant application as filed. It is noted that PNA type backbone embodiments are the only specific types described in the instant specification, as filed, that are examples of non-naturally occurring backbone structures. The broad backbone wording given as "non-naturally occurring backbone structure" is noted as having written basis in instant claim 1, as filed, but is only enabled regarding synthetic methodology etc. regarding PNA type backbones formed via peptide bond formation chemical syntheses.

Claims 11-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. It is noted that instant claim 1 etc. has previously been amended to require the admixture of a target molecule. This amendment was previously submitted in order to limit the claim such that synthetic forms of the nucleic acid mimics would not be within the scope of the claims. These synthetic forms may contain sterically bulky protective groups. These protective groups are generally removed prior to utilization in a method wherein mixing with target molecules is practiced. Instant claim 11, lines 47-48 and 51, contain the phrases "activated derivative of..." and "amino protecting groups", respectively. Consideration of the instant disclosure as filed has failed to reveal written basis for admixtures with target molecules wherein the "activated..." or "amino protecting groups" remain on the mimics of the invention. These limitations, therefore, in claims 11 etc. contain NEW MATTER as disclosing mimic forms with protecting or activated groups thereon when in said admixture. Instant claims 20 and 21 have been included herein because the terminal R^1 group given as COCH_3 is deemed a protective group as discussed above.

Claims 2 and 11-21 are rejected, as discussed below, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, line 7, cites R' as comprising 3 atoms wherein one

selection is H. This H selection appears to be one atom. How can R' be 3 atoms and be selected as H? This same unclarity exists in claim 13, line 6. Clarification of this conflict is requested.

Claim 11, lines 18 and 27, cite the definition of R³ and R⁴ as "as defined above". Consideration of the entirety of claims 11 and 1 from which claim 11 depends has failed to reveal any definition of these R groups. These R groups therefore lack antecedent basis and also lack definition of their metes and bounds. It is noted that claims 20 and 21 also contain these undefined R groups.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a),

the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-6, 11-17, 20, and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Shah et al. (P/N 5,705,333) taken in view of either Webb et al. [JACS 108:2764 (1986)], Summerton et al. [JMB 122:145 (1978)], Inoue et al. [NAR 13:7119 (1985)], or Klevan et al. (P/N 4,828,979).

Shah et al. disclose the practice of PENAMS which are PNA-type backbone based nucleic acid mimics in the entire disclosure. These mimics contain non-natural backbones in the polymers with nucleotidic sidechains as summarized in the abstract. In column 6, lines 60-63, these side chains are described as capable of engaging in hydrogen bonding with corresponding bases on a target nucleic acid. The bridging paragraph between columns 8 and 9 describe these side chains as including purine and pyrimidine base analogs also including those described below as well as in the art. This supplied motivation and suggestion to practice a variety of base analogs therein as are known in the art. Shah et al. describe several specific base analogs in column 10, line 12, through column 11, line 8, with citations to references detailing some of them. The above listed references by Webb et al.,

Summerton et al., and Inoue et al.; are references numbered 47, 46, and 45; respectively, in column 38 of Shah et al. and pointed to in said column 10 description of analogs. The above reference by Klevan et al. is not pointed to specifically in Shah et al. but is another base analog example from the prior art wherein a sterically bulky substituent is attached to a nucleobase and subsequently utilized in hybridization methodology. The PENAMs of Shah et al. are utilized in various hybridization formats including duplex formation as well as triplex formation as summarized in columns 18-23. Such formats require some type of mixing between the PENAMs and target molecules as required in instant claims 1 etc. Shah et al. describes a variety of backbone chain types via the monomeric units of which these backbones are composed as given in column 9, line 48, through column 10, line 11. Spacer groups in this backbone as summarized in column 8, lines 33-61, inclusive of alkyl chain spacers, for example. These backbones include those cited in instant claims 11 etc.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the instant invention because Shah et al. describes a variety of nucleic acid (PNA type) mimics and suggests and motivates the practice of a wide variety of nucleobase analogs within these polymers for hybridization reactions thus resulting in the

practice of the instant invention. A number of these sterically bulky base analog examples are disclosed in Webb et al., Summerton et al., Inoue et al., and Klevan et al.

The disclosure is objected to because of the following informalities:

In the specification on page 14, line 10, the word "thos" appears to be misspelled.

Appropriate correction is required.

Several references are cited on the enclosed PTO Form 892 wherein copies have not been sent with this office action. These citations are included on said Form 892 to make them of official record as having been considered. These references were cited on a PCT search report, filed 10/6/97, but not listed previously on either a Form 1449 or 892. Urdea et al. is cited on the enclosed PTO Form 892 as being of interest in the instant application due to citing sterically bulky attached groups onto nucleobases of the polynucleotides therein discloses. The attachment site is shown as given in column 8, lines 49-64.

No claim is allowed.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to

Serial No. 08/612,661

- 9 -

Art Unit: 1634

Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

April 14, 1998

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER